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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,294	04/12/2004	Kent Voorhees	022116.0102PTUS	4536
24283	7590	12/03/2007	EXAMINER	
PATTON BOGGS LLP			LUCAS, ZACHARIAH	
1801 CALIFORNIA STREET				
SUITE 4900			ART UNIT	PAPER NUMBER
DENVER, CO 80202			1648	
			MAIL DATE	DELIVERY MODE
			12/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,294	Applicant(s) VOORHEES ET AL.	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23,32-48,50,51,53-58,62-70,73,84-86 and 95-99 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,14,15,21-23,37-39,46-48,50,84 and 85 is/are rejected.
- 7) ☒ Claim(s) 4-6,32 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 8-13,16-20,33,35,36,40-45,51,53-58,62-70,73,86 and 95-99.

DETAILED ACTION

1. Claims 1-23, 32-48, 50, 51, 53-58, 62-70, 73, 84-86, 95-99 are pending in the application.
2. In the prior action, mailed on July 23, 2007, claims 1-23, 32-51, 53-58, 62-70, 73, 84-86, 95-99 were pending, with claims 8-13, 16, 17, 33, 35, 36, 40-45, 51, 53-58, 62-70, 73, 86, 95, and 97-99 withdrawn from consideration; and claims 1-7, 14, 15, 18-23, 32, 34, 37-39, 46-50, 84, 85, and 96 under consideration and rejected.
3. In the Response of November 21, 2007, the Applicant amended claims 1, 2, 18, 37-39, 46-48, 84, and 96; and cancelled claim 49.

It is noted that claim 96 has been amended to depend from itself, and has been indicated by the Applicant to be withdrawn. It is assumed that the Applicant intended to amend the claim to depend from withdrawn claim 95. Thus, the claim is now withdrawn from examination.

It is also noted that claims 18-20 have been amended to require that step (b) requires a step of dissociating the progeny phage, which would inherently indicate that it is not the progeny phage that is being detected in step (c) of the claim. See e.g., description of Figure 6 on pages 21-22 and 25 of the application. Rather, as was indicated in the prior action (see, last sentence of second paragraph of item 8 on page 5 of the prior action), by requiring the dissociation of the progeny phage, the claims are implicitly requiring that these claims are drawn to embodiments wherein the material assayed for in part (c) of the claimed methods is a substance associated with a progeny bacteriophage. As amended, these claims therefore read on a non-elected species. Amended claims 18-20 are therefore withdrawn from consideration.

4. Claims 1-7, 14, 15, 21-23, 32, 34, 37-39, 46-48, 50, 84, and 85 are under consideration.

Drawings

5. **(Prior Objection- Withdrawn)** The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include reference character(s) not mentioned in the description. In view of the amendments to the drawings and specification, the objection is withdrawn.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **(Prior Rejection- Maintained in part)** Claims 18-23 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims were rejected because it was not clear from the claims what bacteriophage were being dissociated in these claims. I.e., it was not clear if the dissociation was of the parent phage (i.e. a form of removing the parent phage) or was of the progeny phage (such that the detection step would be to detect a substance associated with the progeny phage). Claim 18 has been amended to clarify that it is the progeny phage that is being dissociated. In view of this, the rejection is withdrawn from claims 18-20, which, as described above, are also now withdrawn as directed to a non-elected species.

However, the rejection is maintained over claims 21-23. This is because, while the Applicant asserts that the amendments to claim 1 and 18 overcome the rejection, there is nothing in claim 21 to indicate whether it is the parent or the progeny phage that are being dissociated.

8. **(Prior Rejection- Withdrawn)** Claims 37-39, 46-50, 84, and 85 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite because it was not clear from the claims if the inclusion of the language "to create a detectable amount of" phage in claims 37 and 46 was intended to require that only an undetectable amount of parent phage was added to the sample, or if the claim language was intended to indicate that a detectable amount of progeny phage was produced independent of the amount of parent phage added to the sample. In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 102 and 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **(Prior Rejection- Withdrawn)** Claims 43-48 and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Takahashi et al. (WO 98/08944- the specification of which is translated in U.S. 6,322,783). As noted by the Applicant, this rejection was directed to claims 46-48 and 50, and not to withdrawn claims 43-45. In view of the amendment of claim 46 and the arguments presented pursuant thereto, the rejection is withdrawn.

11. **(Prior Rejection- Restated as Necessitated by Amendment and Maintained)** Claim 49 was rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (supra) in view of

U.S. 5,789,174 (Mouton). Claim 49 has been cancelled, but the limitations of this claim have been incorporated into claim 46 (from which claim 49 previously depended). Thus, the rejection is restated as a rejection of claims 46-48 and 50 over the teachings of the cited references.

The Applicant traverses the rejection of the claims on the basis that a combination of Mouton and Takahashi would result in a different method from that claimed would be achieved. The argument is not found persuasive. As indicated in the prior action, Mouton is relied upon to show that it would have been obvious to those of ordinary skill in the art to have run a negative control assay in parallel to the test assay. While a literal combination of methods of Mouton and Takahashi may result in a different method from that claimed, such a literal combination is not the limit of what would be obvious based on the teachings of these references. The fact that Mouton indicates that it was known in the art to run negative control assays is sufficient to demonstrate that it would have been obvious to those of ordinary skill in the art to create such a control assay for assays in general, including the method described by Takahashi. The Applicant's argument in traversal is therefore not found persuasive, and the rejection, as restated, is maintained.

12. **(Prior Rejection- Withdrawn)** Claims 1-3, 6, 14, 15, 18-23, 32, and 96 were rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rees et al., (WO 92/02633). Applicant's arguments in traversal of the rejection are found persuasive. The rejection is therefore withdrawn.

13. **(Prior Rejections- Withdrawn)** Claims 4, 5, 7, 37-39, 84, and 85 were rejected under 35 U.S.C. 103(a) as being unpatentable over Rees as applied against claims 1-3, 6, 14, 15, 18-23,

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32, and 96 above, and further in view of Rittenburg et al., (U.S. 5,710,005). Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rees as applied to claims 1-3, 6, 14, 15, 18-23, 32, and 96 above, and further in view of Ulitzur et al. (EP 0 168 933) and of Bittner et al. (EP 0 439 354) Applicant's arguments with respect to the Rees reference were found persuasive. The rejections are therefore withdrawn.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

15. Applicant was advised in the prior action that, should claim 2 be found allowable, claim 96 would be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. In view of the amendment of claim 96, the advisory is now moot.

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application

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claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

17. **(Prior Rejections- Withdrawn)** Claims 1-3, 6, 7, 14, 15, and 96 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425. Claims 18-23 and 32 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425 in view of Rees et al. (supra). Claims 4, 5, 37-39, and 85 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 7,166,425 in view of Rittenburg et al. (supra). In view of the Terminal Disclaimer filed on November 21, 2007, the rejections are withdrawn.

18. **(Prior Rejection- Maintained)** Claims 1-3, 7, 14, 15, 37-39, 84, 85, and 96 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-6, 8-10 of copending Application No. 11/698,673. The rejection is withdrawn from claim 96 in view of the amendment and withdrawal of this claim from consideration.

The Applicant traverses the rejection on the basis that the copending claims require a step of "waiting a predetermined time period such that, it said target microorganism is present in said sample at or above a threshold concentration, a marker will be amplified in the sample." It is noted that copending claims 4 and 5 indicate that the marker may be a bacteriophage (i.e. a progeny phage). Thus, the copending claims inherently disclose an embodiment wherein the time period waited is the time period required for the parent bacteriophage to multiply in the target microorganism, if present, to create an increased number of bacteriophage (i.e. progeny phage). While the present claims do not explicitly require a step of waiting, they do require a step of providing conditions to allow progeny phage to be produced, which would inherently require waiting a time period sufficient for the phage to reproduce- thereby amplifying the marker (i.e. the progeny phage). Thus, while the present claims do not have the same language as the copending claims, they nonetheless represent one of the embodiments disclosed by those claims, and therefore represent an obvious variation of the copending claims. Applicant's argument in traversal is therefore not found persuasive, and the rejection is maintained.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claims are allowed.
20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claims are allowed. Claims 4-6, 32, and 34 are objected to for depending on rejected claims.
20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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/Z. Lucas/
Patent Examiner, AU 1648